

REMARKS

Prior to the present Office Action, claims 39-64 were pending. No claims fees are due.

5 The drawings are modified to delete text labels and dimensions, as well as add a number of element numbers. Accordingly, a set of REPLACEMENT drawings with the changes made is attached hereto as well as an ANNOTATED set showing the change made. Changes were only made in sheets 1-29 of 31 sheets.

10 A number of amendments have also been made to the specification, primarily consisting of insertion of text that was previously in the drawings. Certain element numbers have also been added. No new matter has been added.

A new Abstract is also submitted above on a separate sheet as required by Examiner Ranade. A substitute specification with the amendments made to the specification (but without cross outs or interlineations) is attached.

15 Claims 39 and 42 stand rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. Specifically, the Examiner alleges lack of enablement for the element “a transmission in the shaft for transmitting movement of the actuator through elements in the shaft to the port for moving the fastener from its undeployed position to its deployed position and anchoring the port to tissue.” Claim 42 also specifies that the transmission converts motion of
20 the manual actuator into rotational motion about the vertical axis to cause the fastener to rotate. Examiner Renade states that the explicit mention of “gearing or other well known means” is insufficient to enable one of skill in the art to make and use the invention.

In response, Applicants note that there are a number of disclosures of a transmission for transmitting movement of an actuator to movement of the port fastener, and that therefore there
25 is sufficient support for such a claim element. Initially, original claim 37 read as follows:

37. A delivery system for securing a device and associated attaching means to bodily tissue, said delivery system comprising a cover, a plunger, and a slide pusher, *and a transmission, wherein said transmission converts linear motion of said plunger into rotational motion to deploy the attaching means of the device. (italics added)*

30

In addition, the portion of the specification cited by the Examiner reads in full:

The linear motion of the plunger 22 and slide pusher 24 is converted into rotational motion through a transmission using gearing or other well known means. (bottom of ¶0117)

5

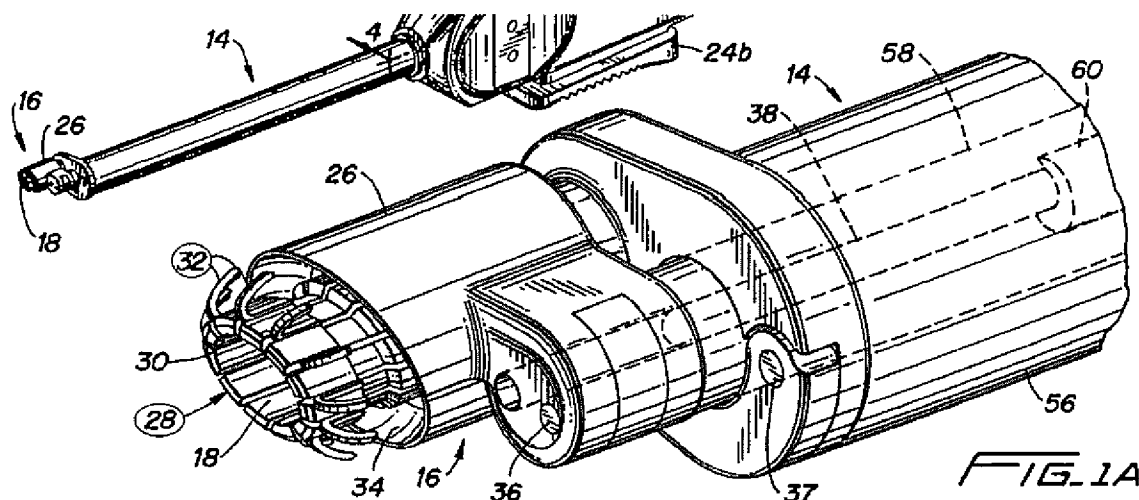
Earlier in the specification, specifically with reference to FIGS. 5-8, an access port delivery system 20 is described wherein upon actuation of a firing means (actuator) a plunger 22 moves in the direction of the access port 10 causing a slide pusher 24 to transfers the movement energy to a slide assembly 26. The slide assembly 26, in turn, is forced in the direction of the access port 10 and causes beams 28 attached to the slide assembly 26 to act upon the fasteners 14, allowing them to rotate into the fascia or other tissue of the patient. (see ¶0091).

Various fastener embodiments are shown and described, as are a number of different actuators or trigger mechanisms. For example, FIGS. 58-62 illustrate a preferred rotating disc 520 fastener system. The disc 520 within the baseplate 510 rotates, thereby causing lever arms 525 to push against curved hooks 501, which in turn rotate about their fixed axis in the baseplate through an arc to their the fully deployed positions. Converting linear motion of a plunger 22 and slide pusher 24 into rotational motion through a transmission to rotate the disc 520 is well within the skill of one in the art. There is thus sufficient support under 35 U.S.C. §112, first paragraph, to enable one of skill in the art to make and use the invention, and Applicants request that the Examiner withdraw the section 112 rejection.

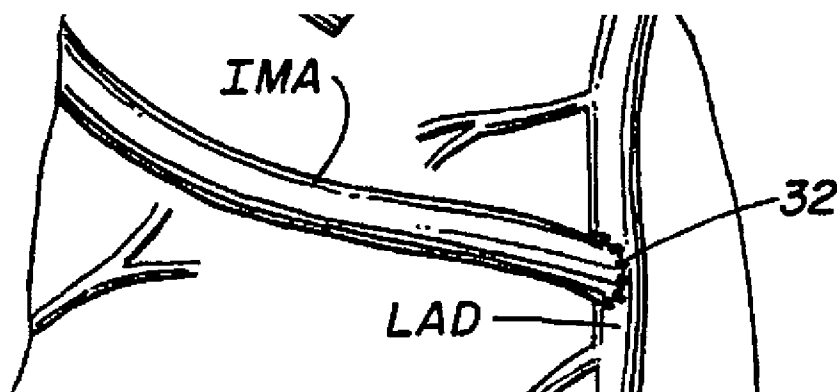
20

Claims 39-64 stand rejected under 35 U.S.C. §103 as being obvious over U.S. Patent No. 5,833,398 to Hinchcliffe in view of U.S. Patent No. 4,781,680 to Redmond. Hinchcliffe discloses a device for forming an anastomotic coupling between one blood vessel and another that intersects the first from the side. One version of the device is shown here, with cited element numbers collet 28 and clips 32 circled:

25



The end result of using the device in Hinchcliffe is a multiple clip connection (in lieu of sutures) between the two blood vessels, as seen below at 32 from FIG. 19:



5

Redmond on the other hand discloses an implantable resealable injection site which is placed subcutaneously and used to introduce drugs or other fluids to the spine or vasculature. Nowhere in Redmond is there any mention of attaching the injection site to tissue, let alone even where the injection site might be located, aside from "subcutaneously."

Applicants respectfully object first to the combination of these two disparate references, and second to the Examiner's assertion that the purported combination obviates the claims.

As to the lack of motivation to make the combination of references, Hinchcliffe does not deal with an implant, and Redmond does not mention fastening the injection site to tissue. The independent claims at issue (39, 48, 57) all recite features of an implantable injection port and deployment tool system, wherein the injection port has at least one incorporated fastener and the deployment tool includes structure for moving the fastener from an undeployed to a deployed

position for anchoring the port to tissue. Applicants question why the device for forming anastomotic couplings of Hinchcliffe provides one of skill in the art motivation to modify the otherwise unfastened injection site of Redmond. Hinchcliffe teaches deploying clips 32 around the end of one blood vessel to secure it to a side opening in another vessel. The clips are the implant, they do not secure any other implantable device in the body, but only connect the two blood vessels. In other words, they are jettisoned from the device (tool). The claims at issue pertain to an injection port with a fastener therein that is deployed by a separate tool. Hinchcliffe does not teach including the clips 32 in another device. Moreover, no mention in Redmond is made of a fastener, leading the Applicants to wonder why one of skill in the art would be motivated to add one, and then why look to Hinchcliffe which is in a different technical area.

The Examiner's stated reason for combining the two references is that "it would have been obvious to include a septum to the housing of Hinchcliffe thereby creating a reservoir in order to provide a more sterile surgical environment." Applicants fail to see why providing a reservoir on the device of Hinchcliffe achieves anything other than getting in the way of the stated purpose, and adding complexity and cost. Likewise for a septum. And as for improving sterility, one might assume that providing a fluid-filled reservoir would actually introduce potential for contamination, and in any event the inert solid structures of the device of Hinchcliffe are certainly sterilizable and not in need of an out-of-place reservoir to improve the sterility situation. No *prima facie* case of obviousness has been stated.

Secondly, Applicants note that even the purported combination of Hinchcliffe and Redmond does not disclose or suggest the claimed elements. Redmond provides an implantable injection site, which includes a housing, septum and reservoir, however no fastener at all, let alone incorporated into the housing. Furthermore, no tool for delivering/deploying the injection site is described. Hinchcliffe provides a device specially designed for deploying a plurality of independent clips in the tissue at a vessel-to-vessel T-junction. There is no implant having a fastener incorporated therein, indeed all that are left in the patient are the clips.

Examiner Renade remarkably states that Hinchcliffe discloses an implantable injection port and deployment tool system. Applicants see no such structure. The Examiner further cites element 28 as the "housing" into which the fastener is incorporated. However, element 28 in Hinchcliffe is a collet that along with an anvil 26 forms a part of an anvil assembly 16. Collet 28 is tubular and receives a section of internal mammary artery (IMA) as seen in FIGS. 11-12.

Interaction between the collet 28 and anvil 26 curls the clips 32 into their final forms securing the IMA to the left anterior descending artery (LAD) , as seen best in FIG. 17 and described at col. 7, line 64 through col. 8, line 7, and at col. 9, lines 23-37. So, the "housing" identified by the Examiner is instead a part of the anvil system that acts on the fasteners 32.

5 Examiner Renade also attempts to track certain other elements of the claims (e.g. upper and lower face of port, tool cover, etc.) to elements in Hinchcliffe. However, Hinchcliffe basically shows a hollow tube having the anvil structure at its distal end. The parallels are not at all apparent, and Applicants respectfully assert that the combination of Hinchcliffe and Redmond is insufficient to obviate the claims.

10 In summary, Applicants believe that claims 39, 48 and 57 are patentable over the cited references.

Examiner Renade details alleged similarities between elements in Hinchcliffe and the dependent claims. Many of these alleged similarities fail partly on the basis that the structure on which the dependent feature is premised (e.g., housing, relative fastener/housing position
15 movement) is not present, and therefore the dependent feature cannot be present or suggested either. Moreover, based on the above remarks Applicants believe that the Examiner has not made out a proper case for obviousness of the independent claims (39, 48 and 57) and thus they along with their dependents are allowable. Consequently, no further explanation of the problems in the rejections will be given.

20 Applicants respectfully request that claims 39-64 be allowed.

Respectfully submitted,

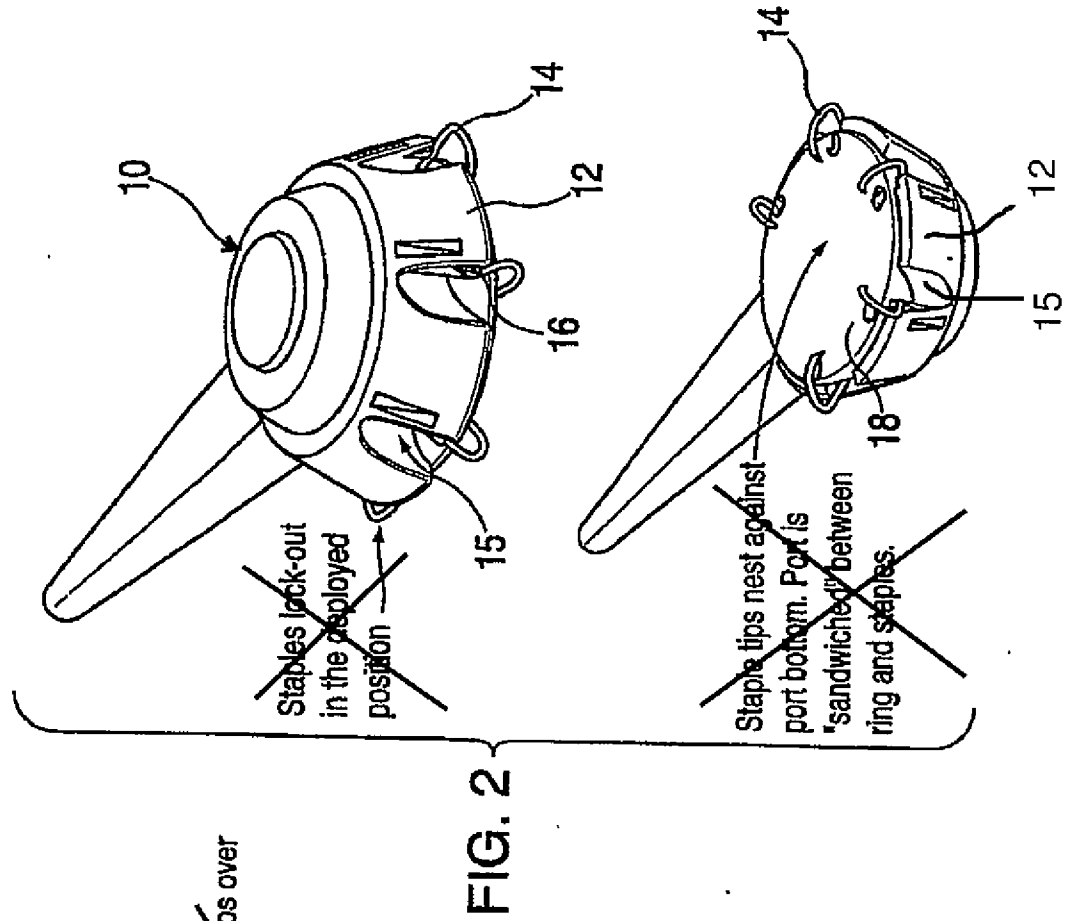
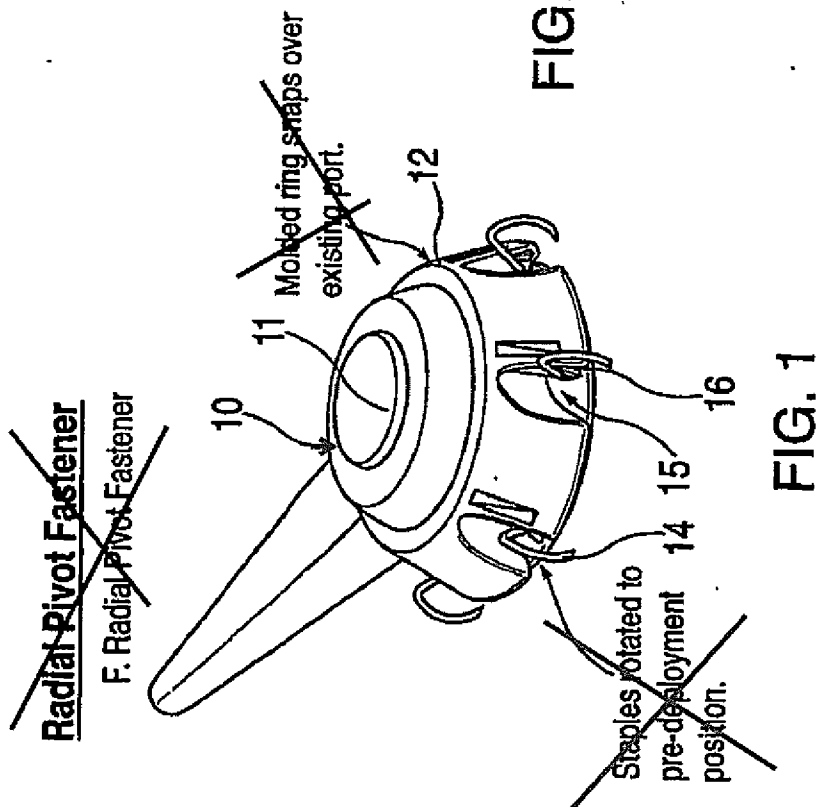
Dated: September 14, 2009

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Registration No. 33,433

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35 Telephone: 714 246 4026
Fax: 714 246 4249



~~Radial Pivot Fastener (detail)~~

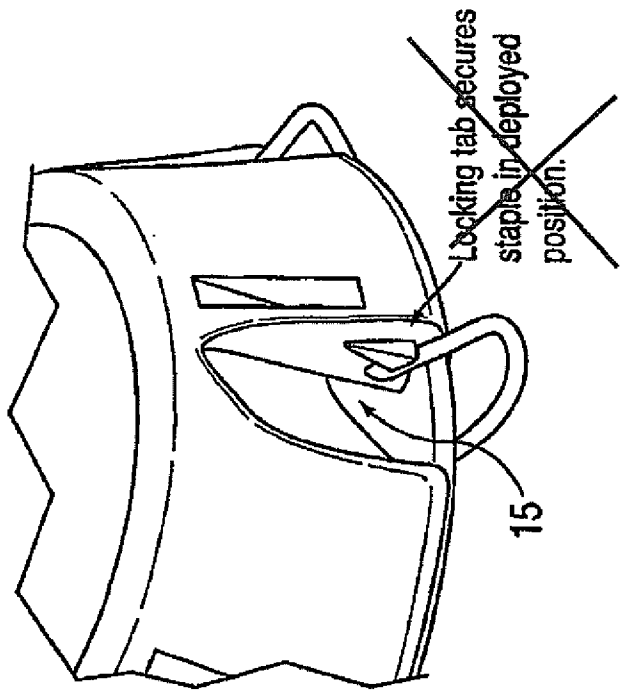


FIG. 4

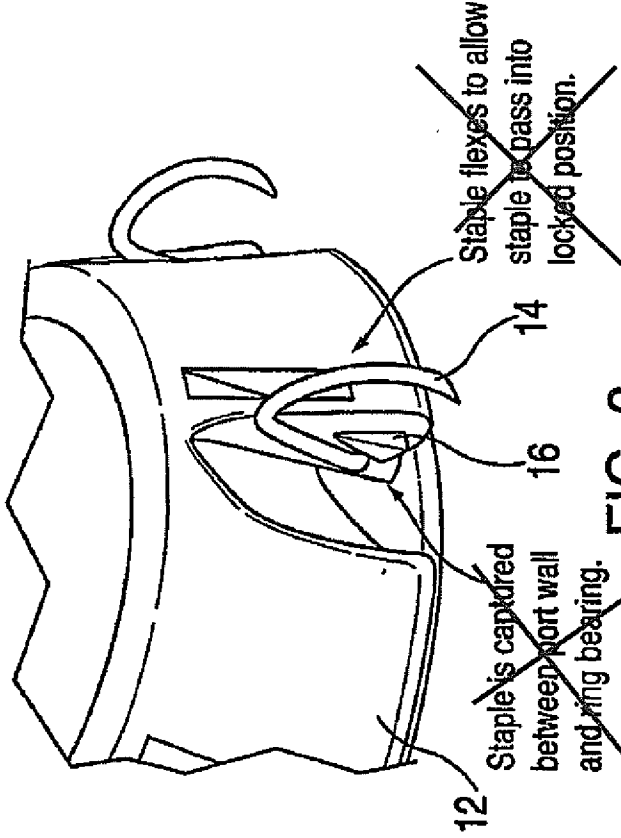


FIG. 3

Port Delivery System (Distal End)

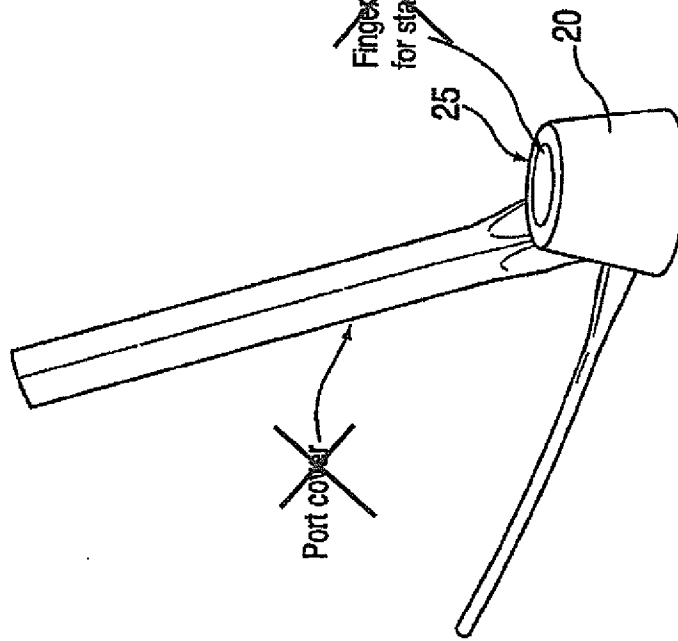


FIG. 5

Delivery System Distal End

- Holds port in delivery location.
- Allows for tactile positioning.
- Deployment instantaneous or controlled by surgeon.

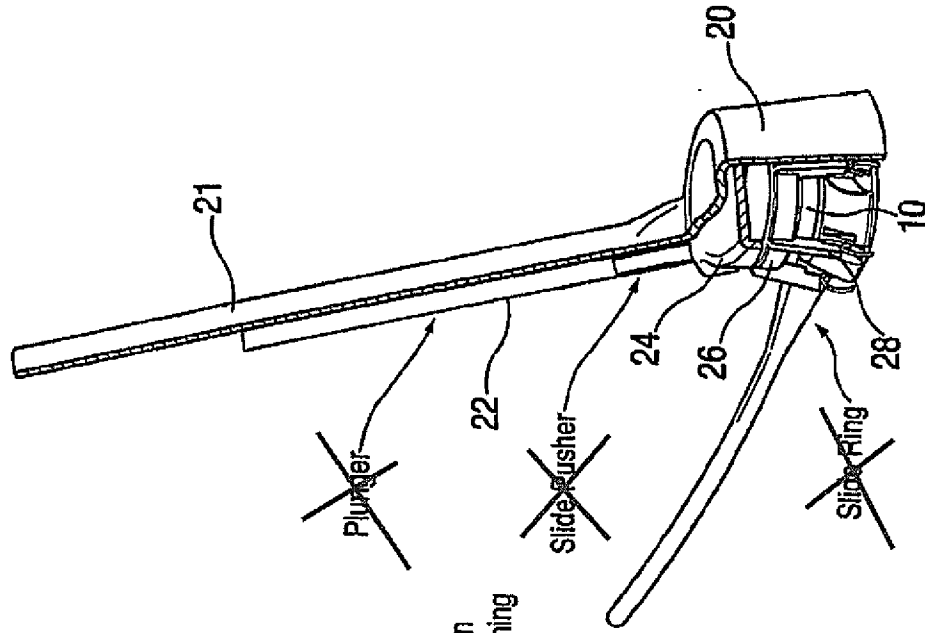
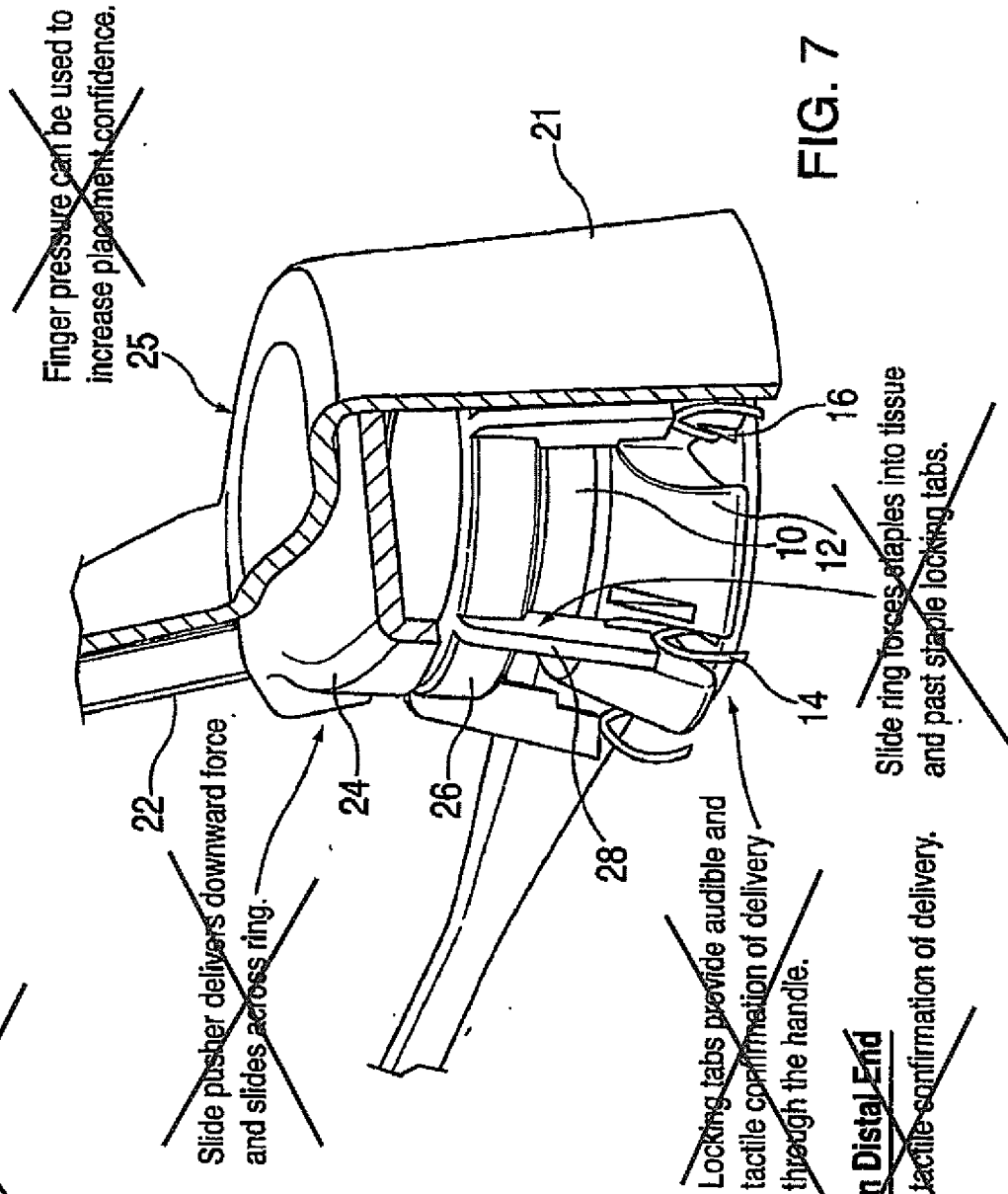


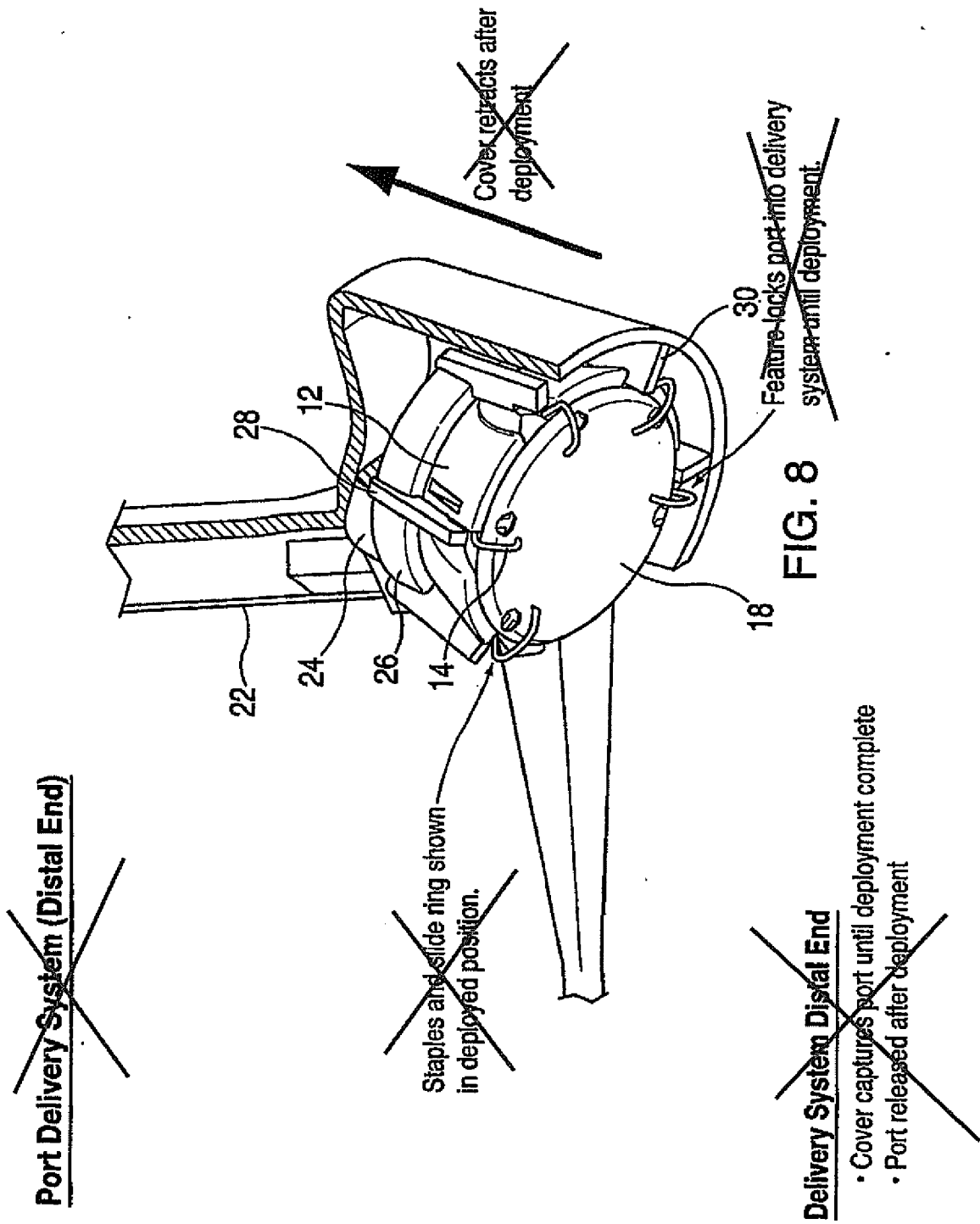
FIG. 6

~~Port Delivery System (Distal End)~~



~~Delivery System Distal End~~

- Audible and tactile confirmation of delivery.



~~Port Delivery System (handle configurations)~~

~~Pencil Grip style~~

~~(shown with shaft at 60°)~~

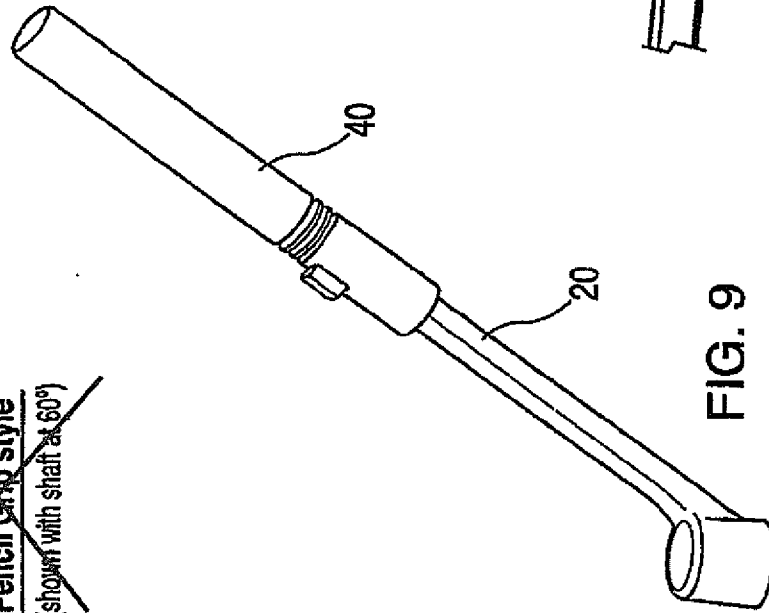


FIG. 9

~~Simple Button/Trigger Release mechanism~~

- ~~• Produces ~0.250 - 0.750" rod travel (depends on force requirement)~~
- ~~• Deployment instantaneous, high impact speed~~

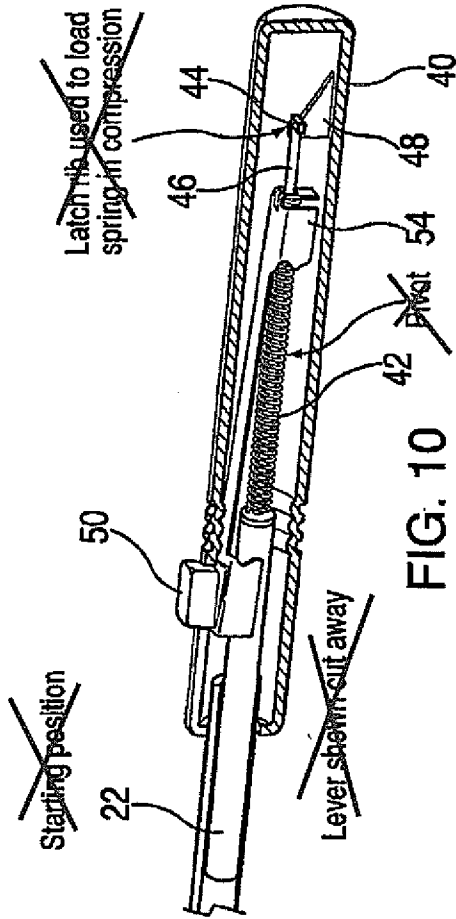


FIG. 10

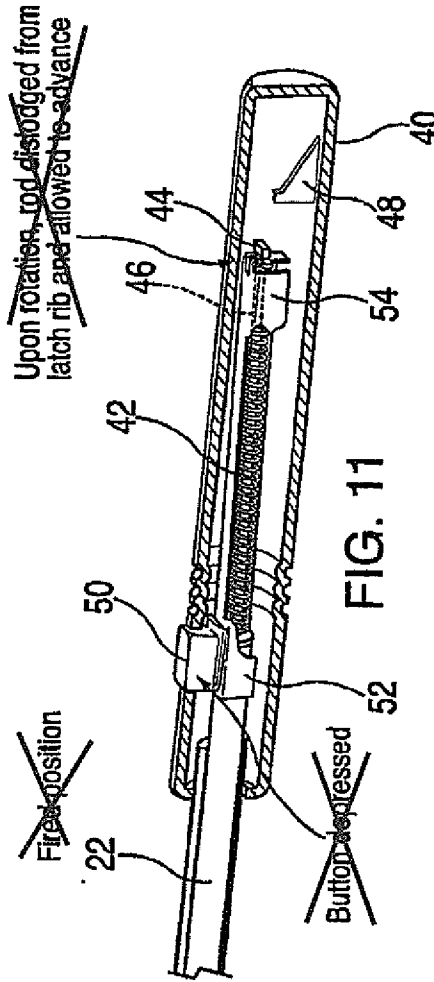


FIG. 11

~~Port Delivery System (handle configurations)~~

~~Palm Grip style~~

~~(shown with shaft at 60°)~~

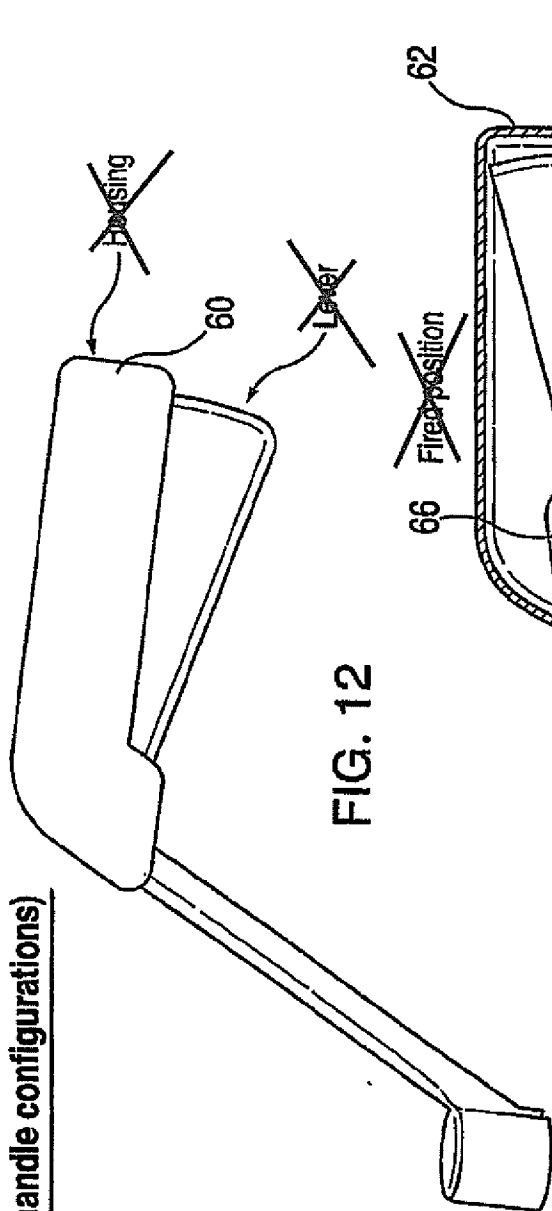


FIG. 12

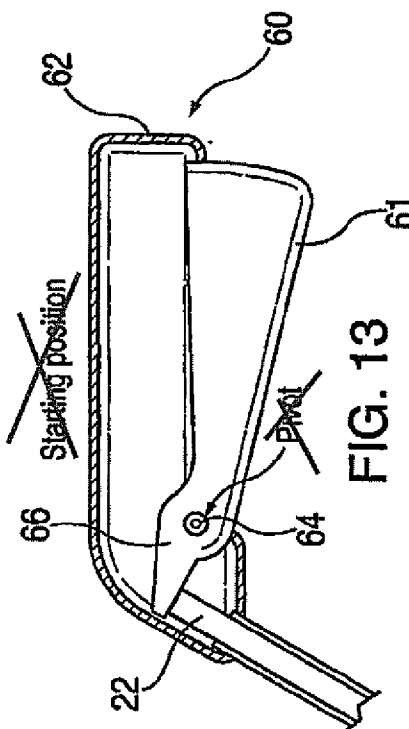


FIG. 13

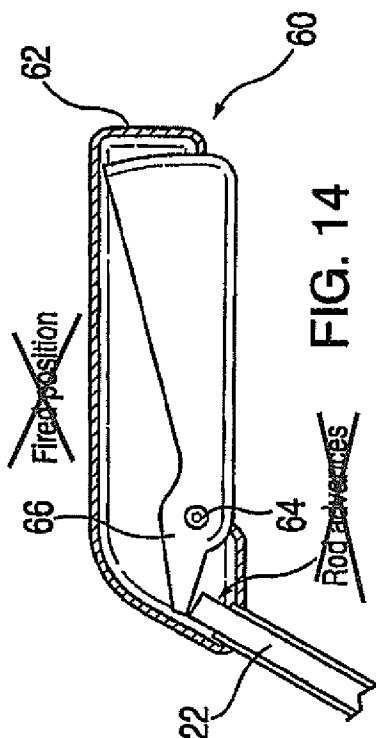


FIG. 14

~~Lever mechanism~~

- ~~• Produces ~ 0.250" rod travel~~
- ~~• Can produce in excess of 50lb. force on rod (depends on force requirement)~~
- ~~• Deployment speed controlled by operator~~

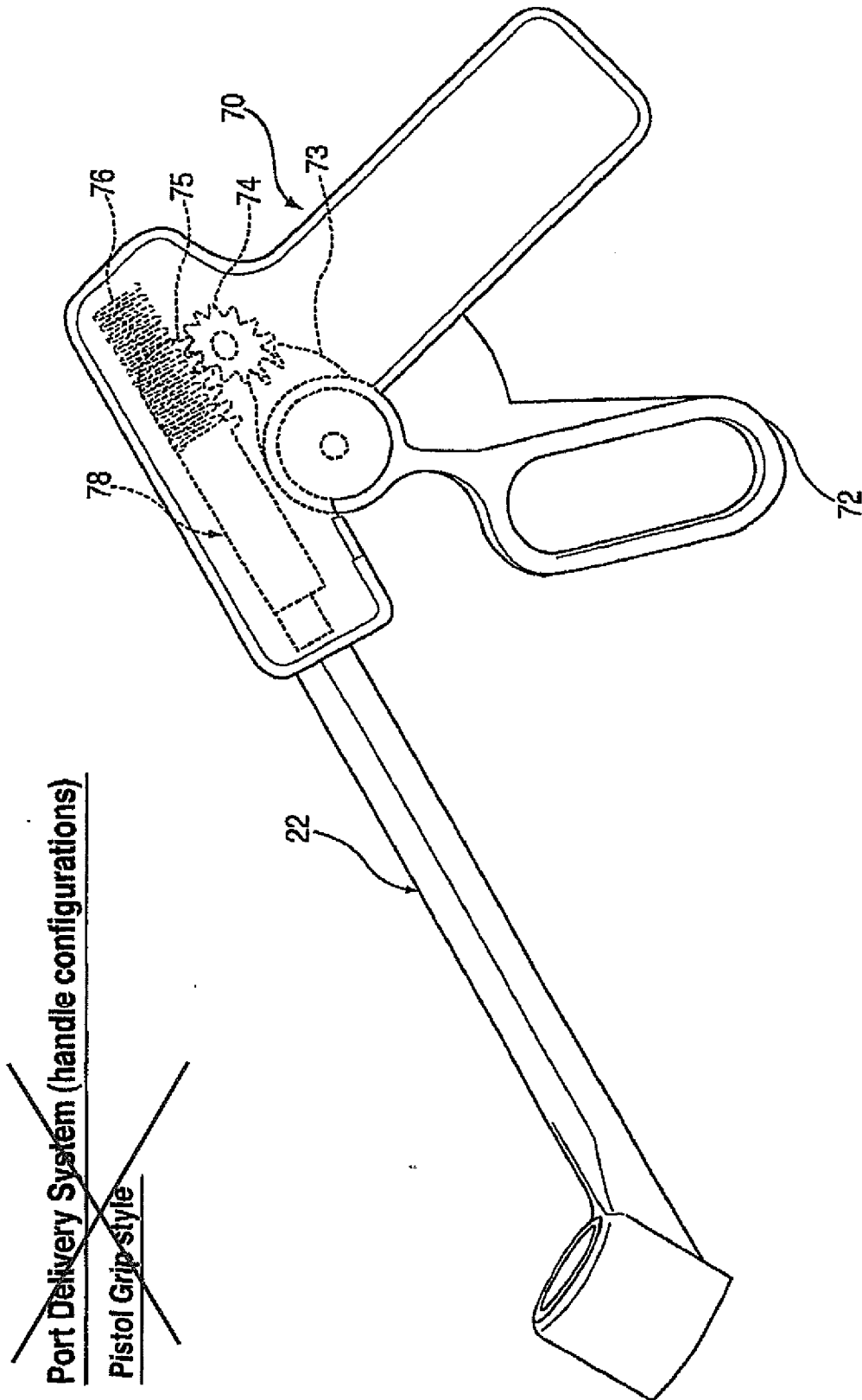
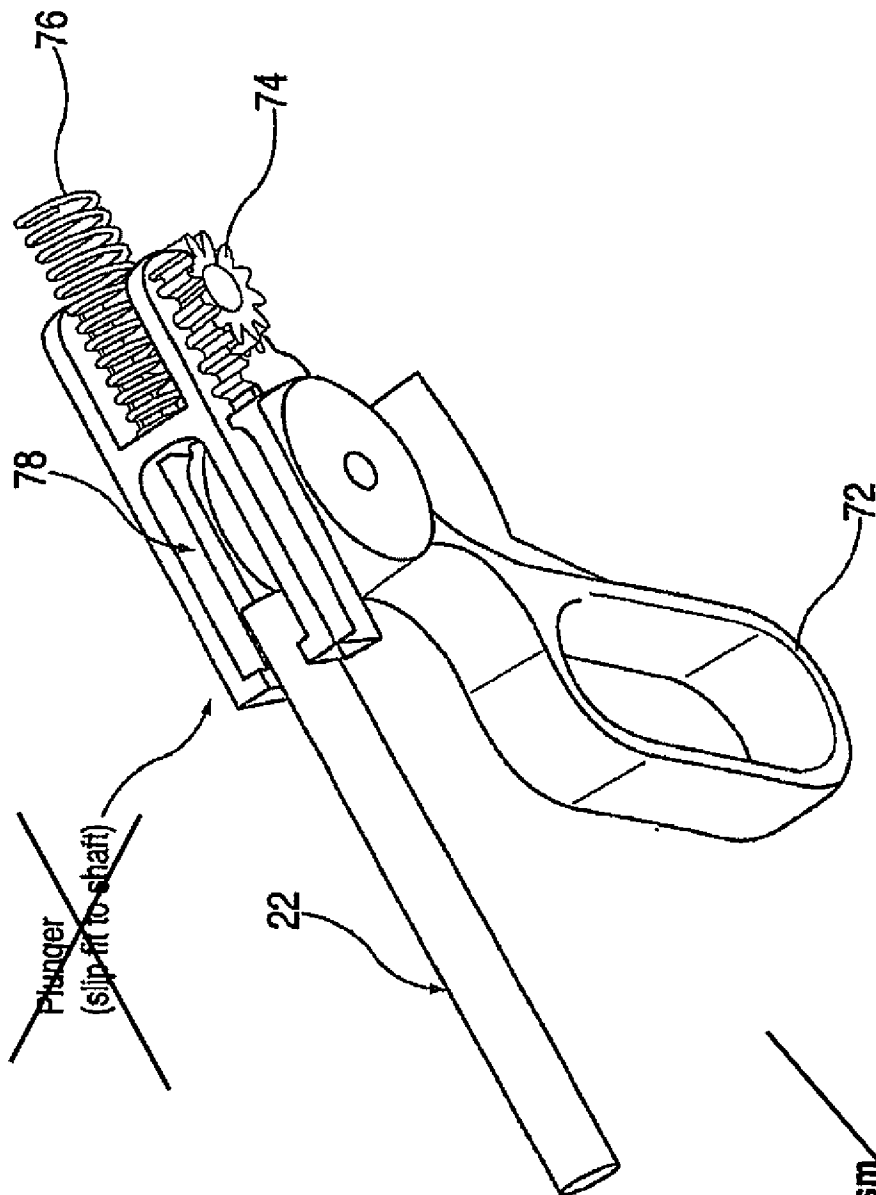


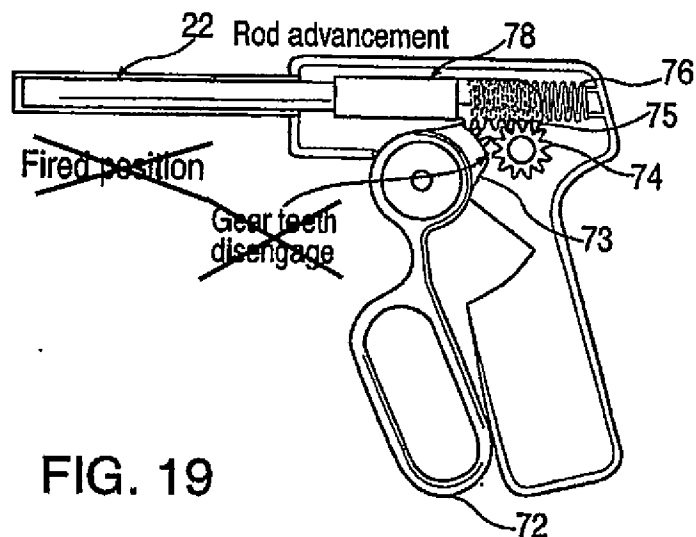
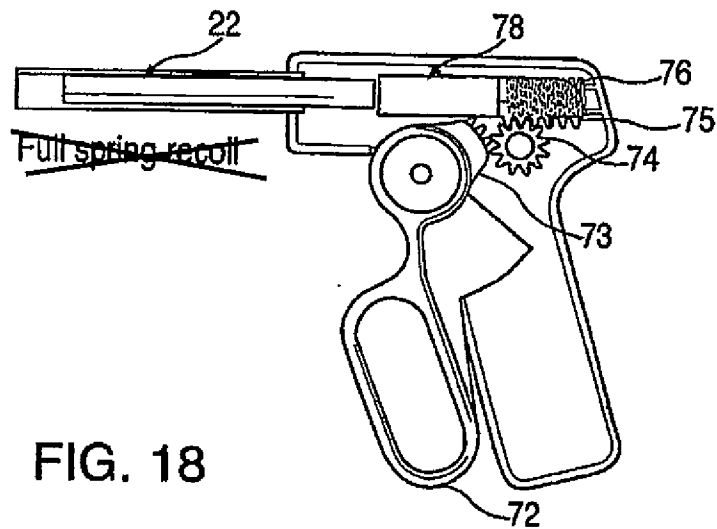
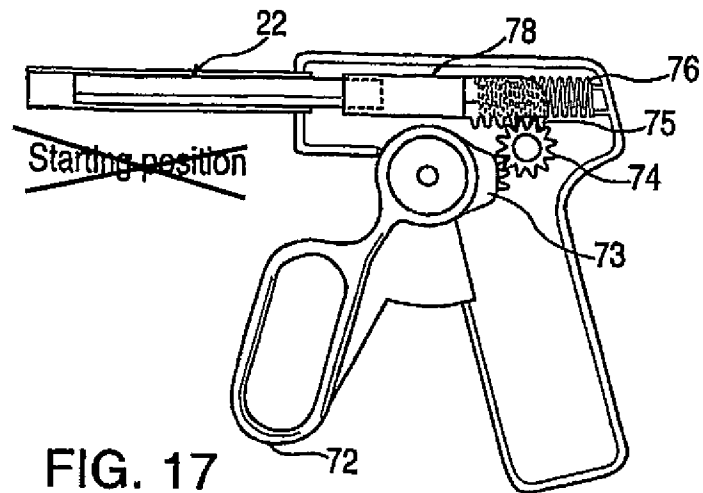
FIG. 15



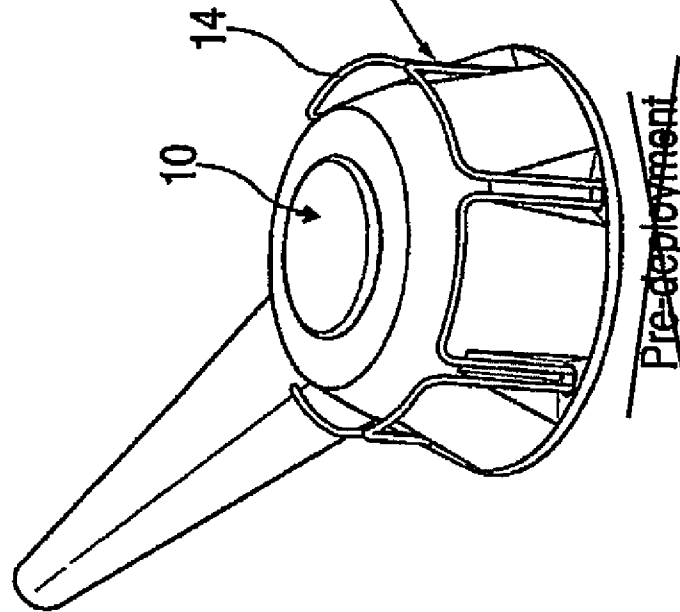
~~Gear train mechanism~~

- ~~• Produces ~0.400" rod travel~~
- ~~• Can produce ~50lb. force on rod~~
- ~~• Deployment instantaneous, very high impact speed~~

ANNOTATED SHEET SHOWING CHANGES



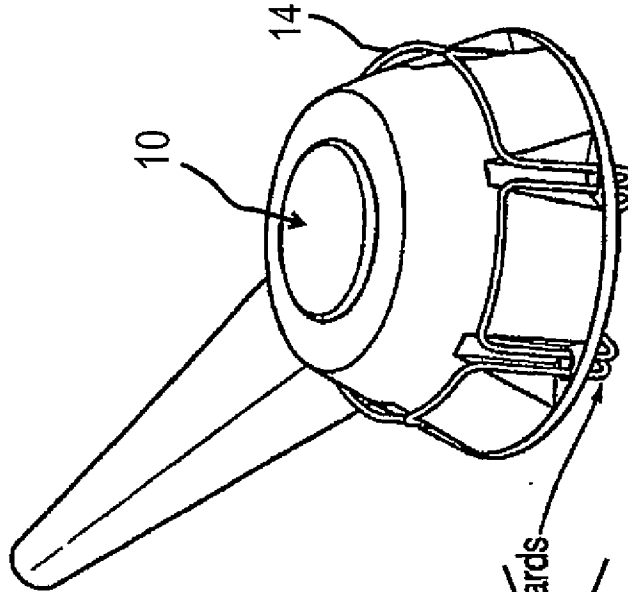
~~Continuous NFI Wire Form~~



~~Legs constrained
in delivery system.~~

~~Pre-deployment~~

FIG. 20



~~Legs deploy towards
center of port.~~

~~Post-deployment~~

FIG. 21

Continuous Wire Form — Possible fastener leg configurations

A1. Continuous Wire Form: Straight Leg Blunt Tips

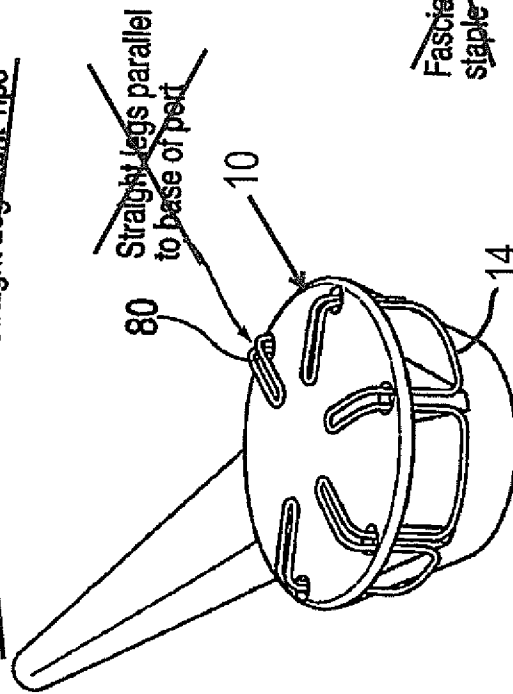


FIG. 22

A2. Continuous Wire Form: Curved Leg, Blunt Tips

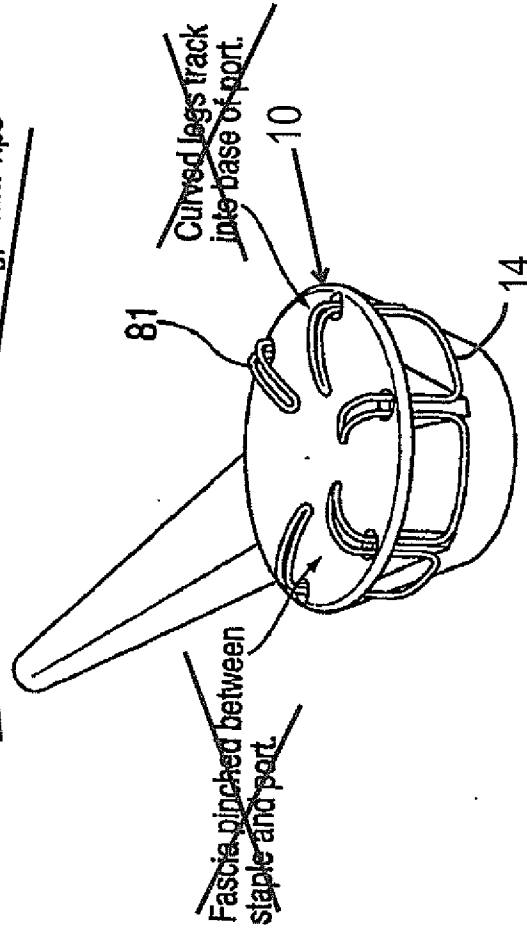


FIG. 23

~~Continuous Wire Form Possible fastener leg configurations~~

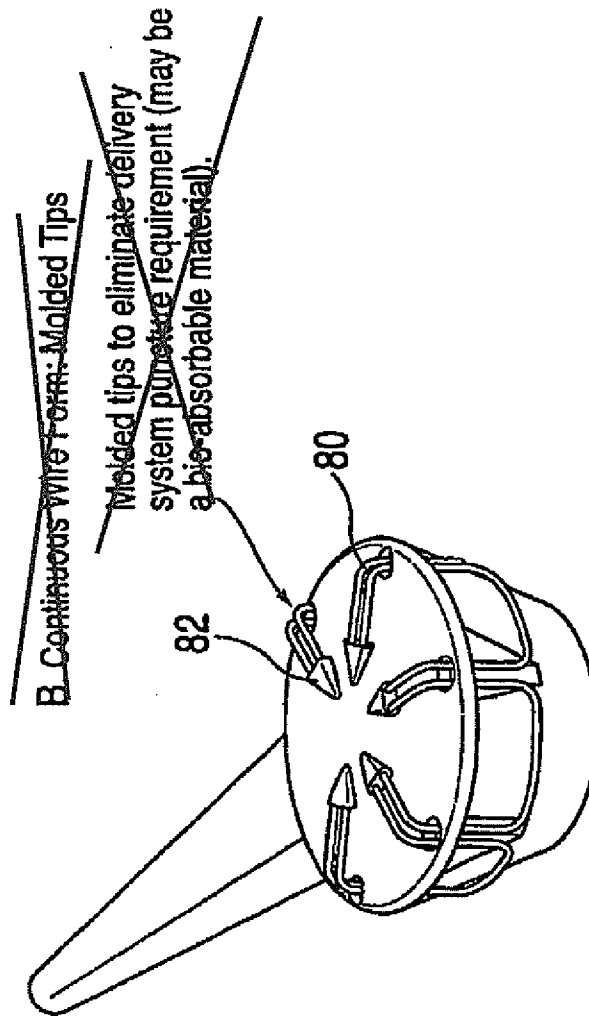


FIG. 24

~~Continuous Wire Form Modified~~

~~C. Continuous Wire Form Ground Tips~~

~~Insert-molded ring
required to keep
individual segments as
one part.~~

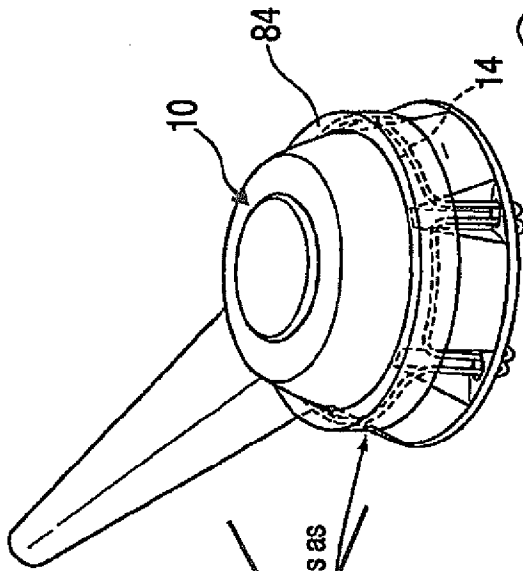


FIG. 26

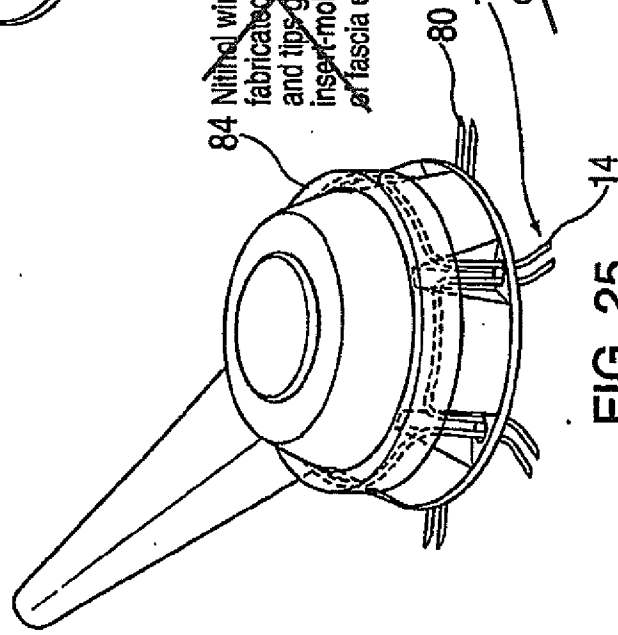


FIG. 25

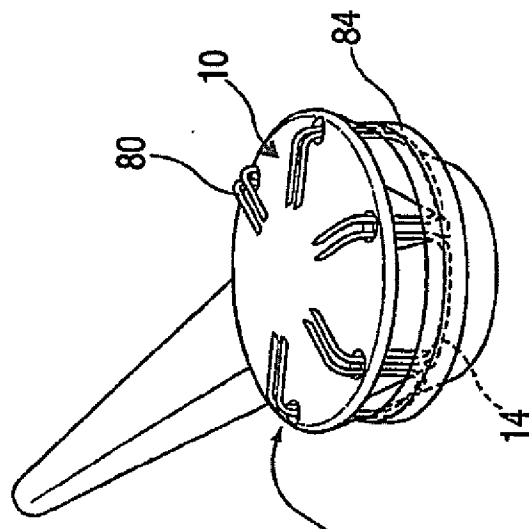
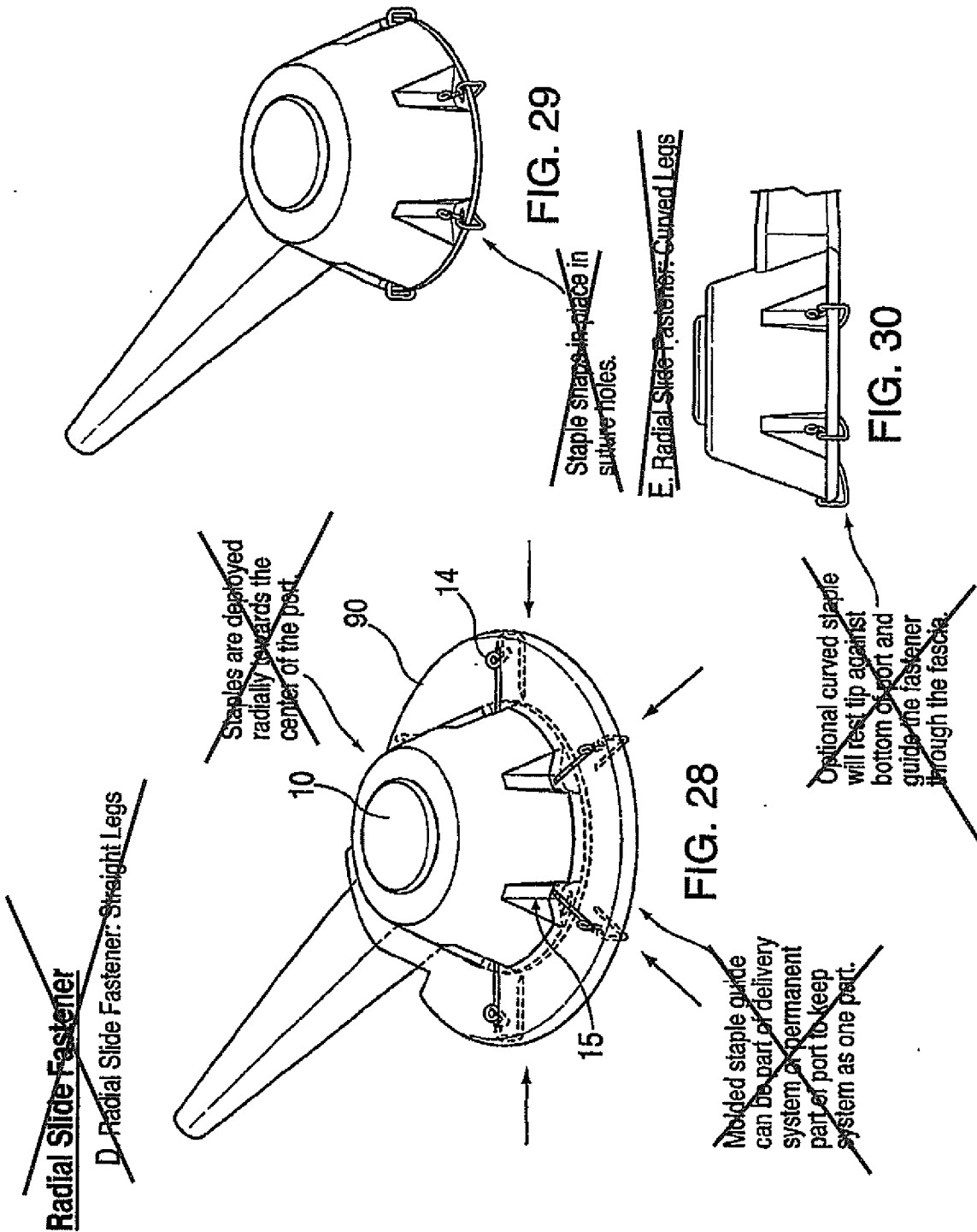


FIG. 27

~~84 Nitinol wire form
fabricated as one-piece
and tips ground after
insert-molding for ease
of fascia entry.~~

~~tips can face internally
or externally.~~



~~Two Part Fastening System: Concept 2~~

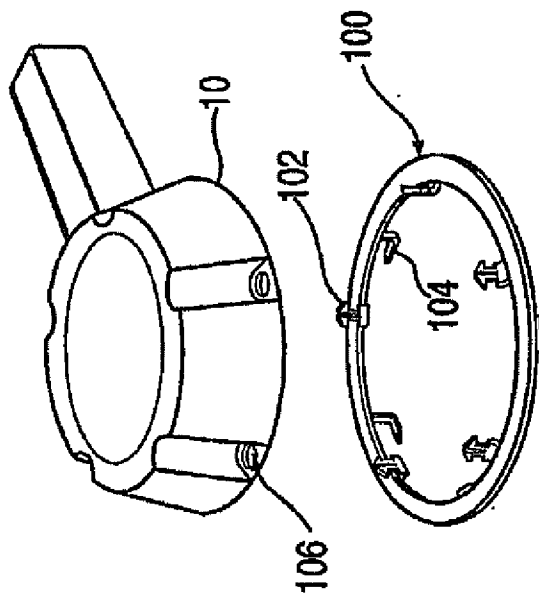


FIG. 31

~~Pre-Installation~~

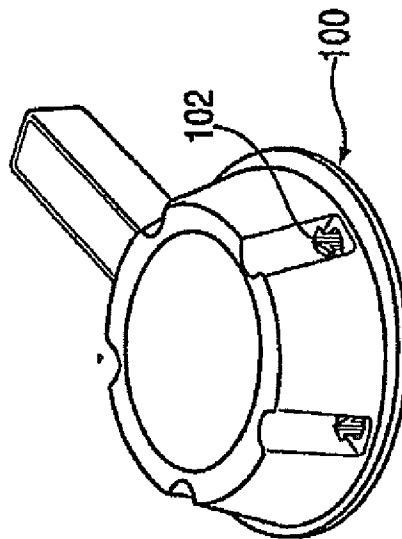


FIG. 32

~~Post-Installation~~

~~Two Part Fastening System: Concept 1~~

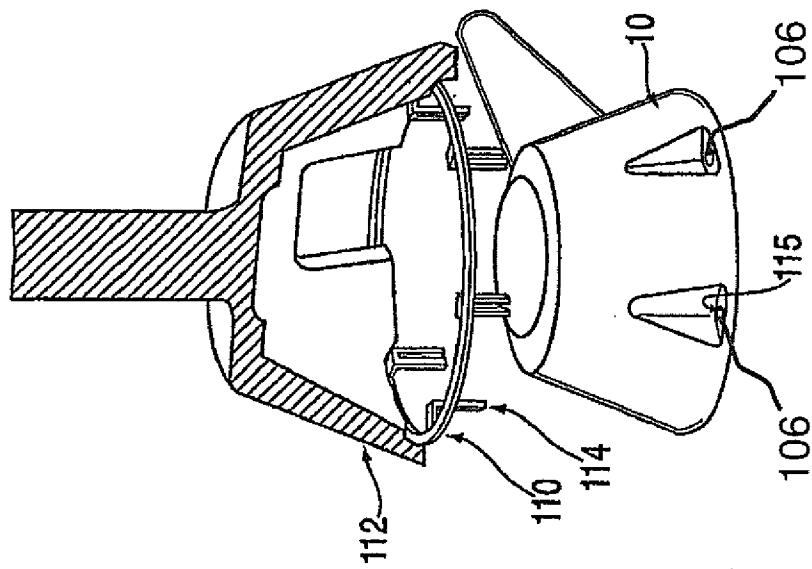


FIG. 33

~~Pre-installation~~

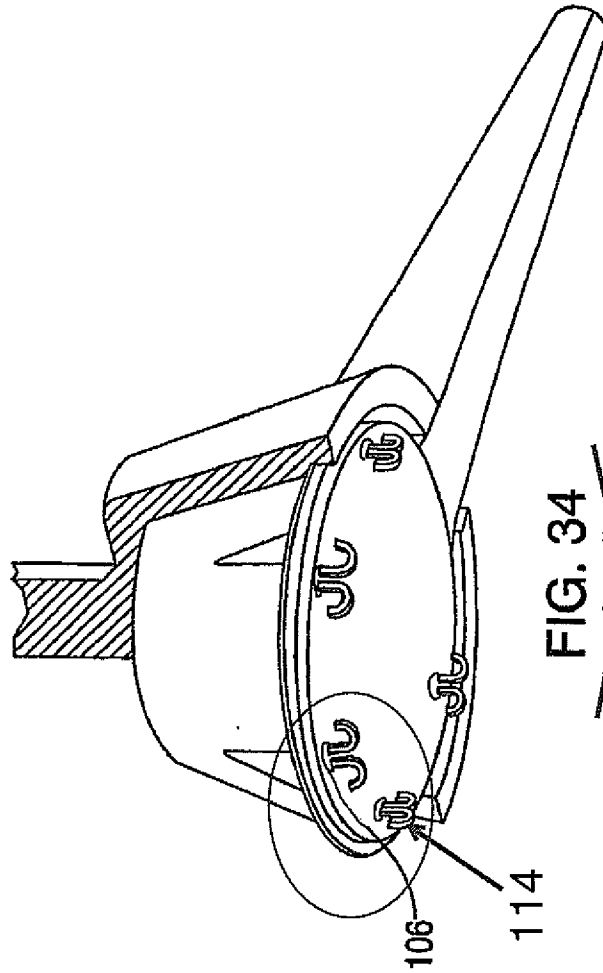


FIG. 34

~~Post-installation~~

~~Stand Alone Fastener: Concept 1~~

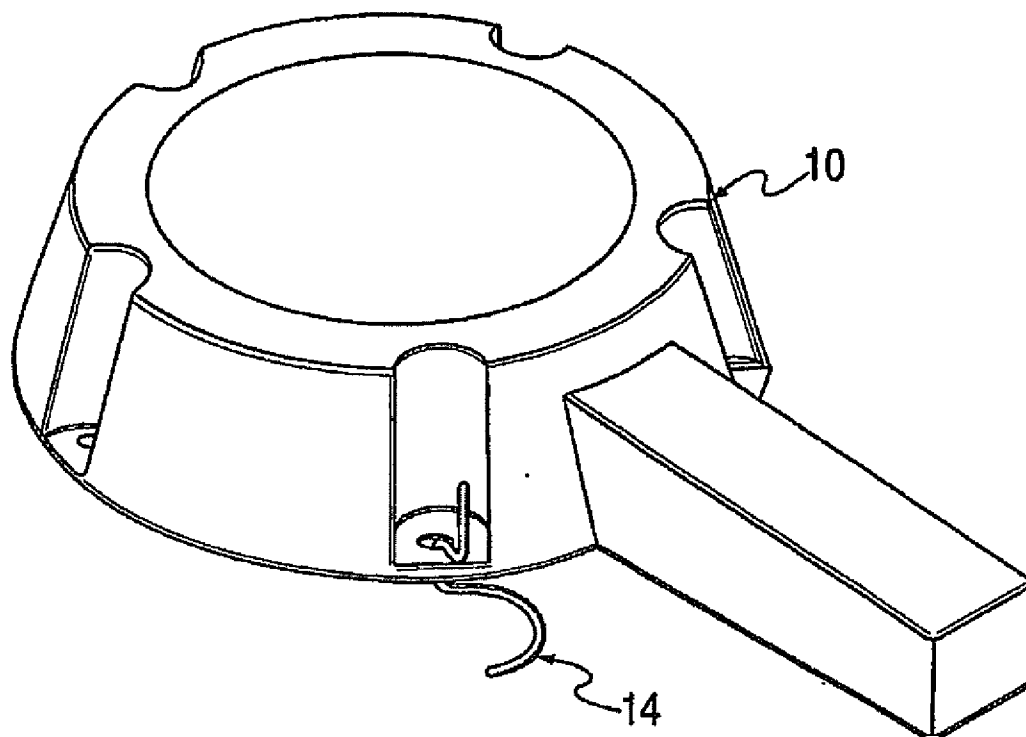


FIG. 35

~~Stand Alone Fastener: Concept 2~~

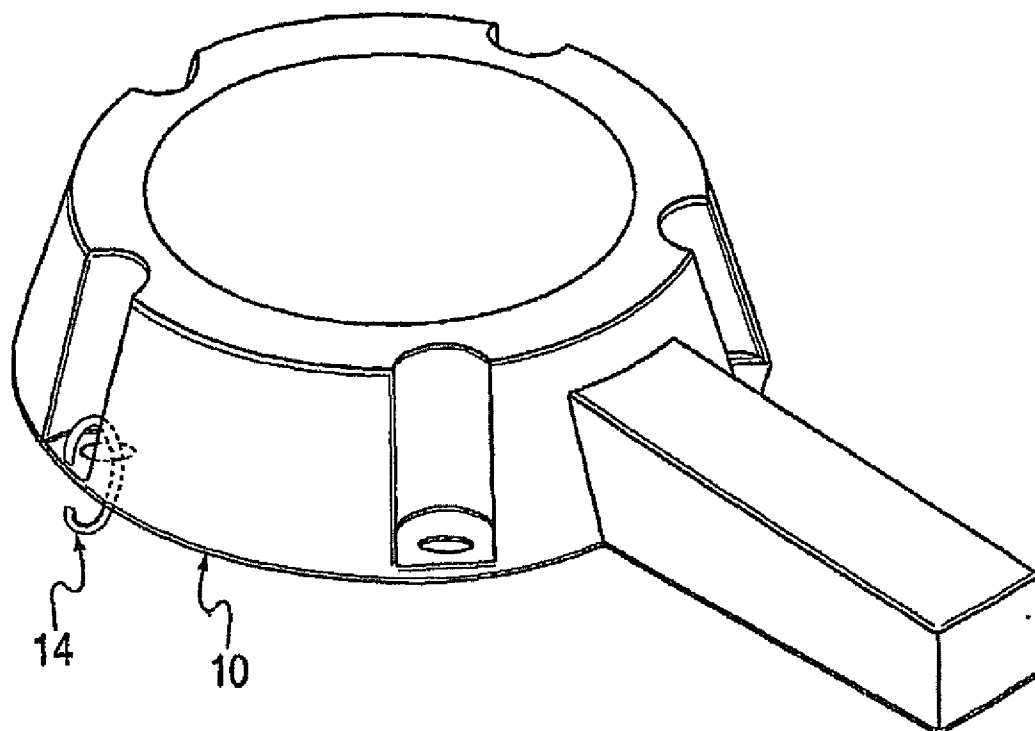


FIG. 36

~~Stand Alone Fastener-Concept 3~~

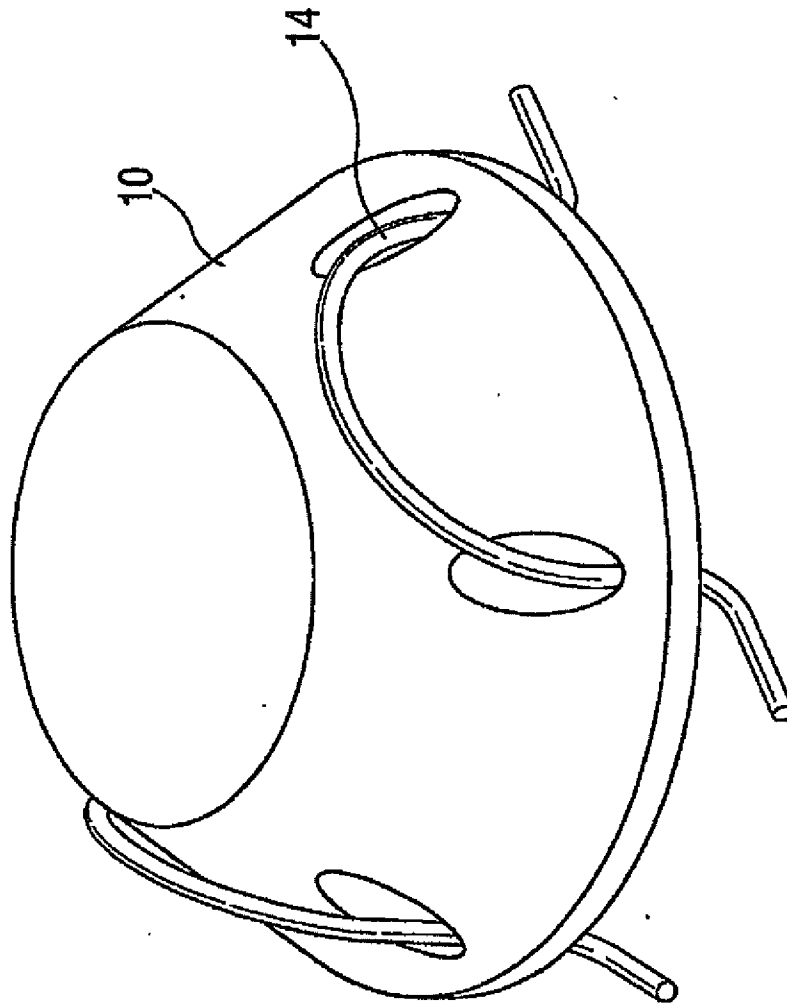


FIG. 37

~~Stand Alone Fastener: Concept 4~~

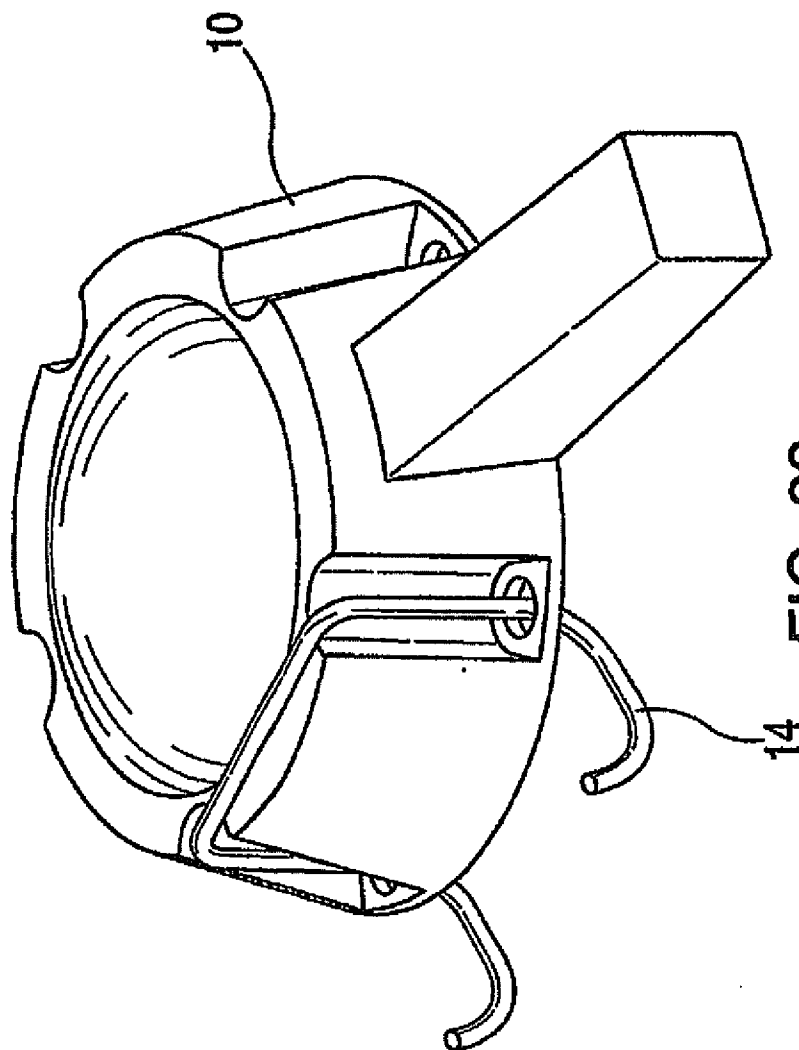
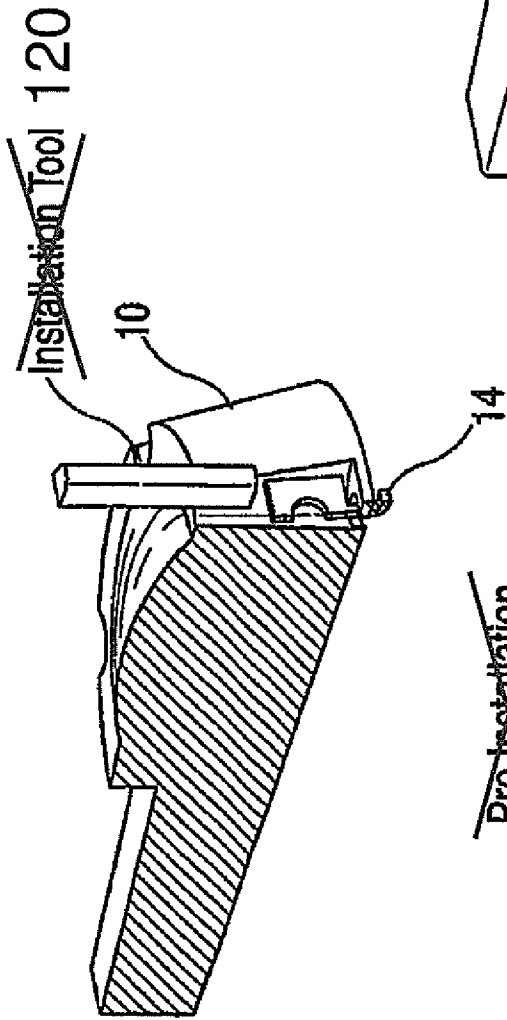


FIG. 38

~~Injection Port Incorporated System~~



~~Pre Installation~~
FIG. 39

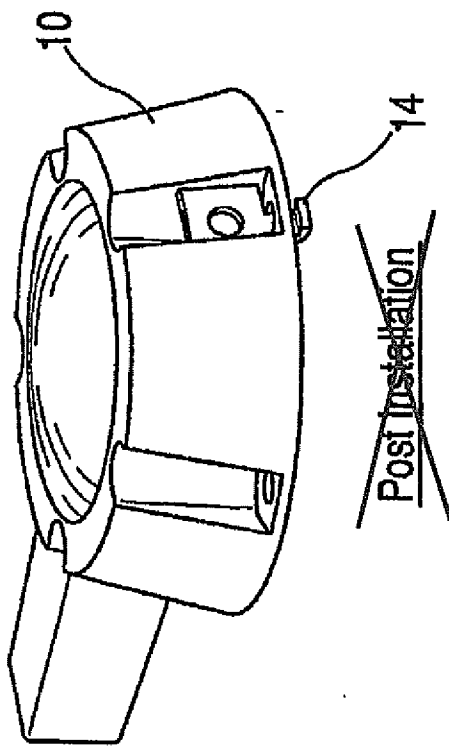


FIG. 40

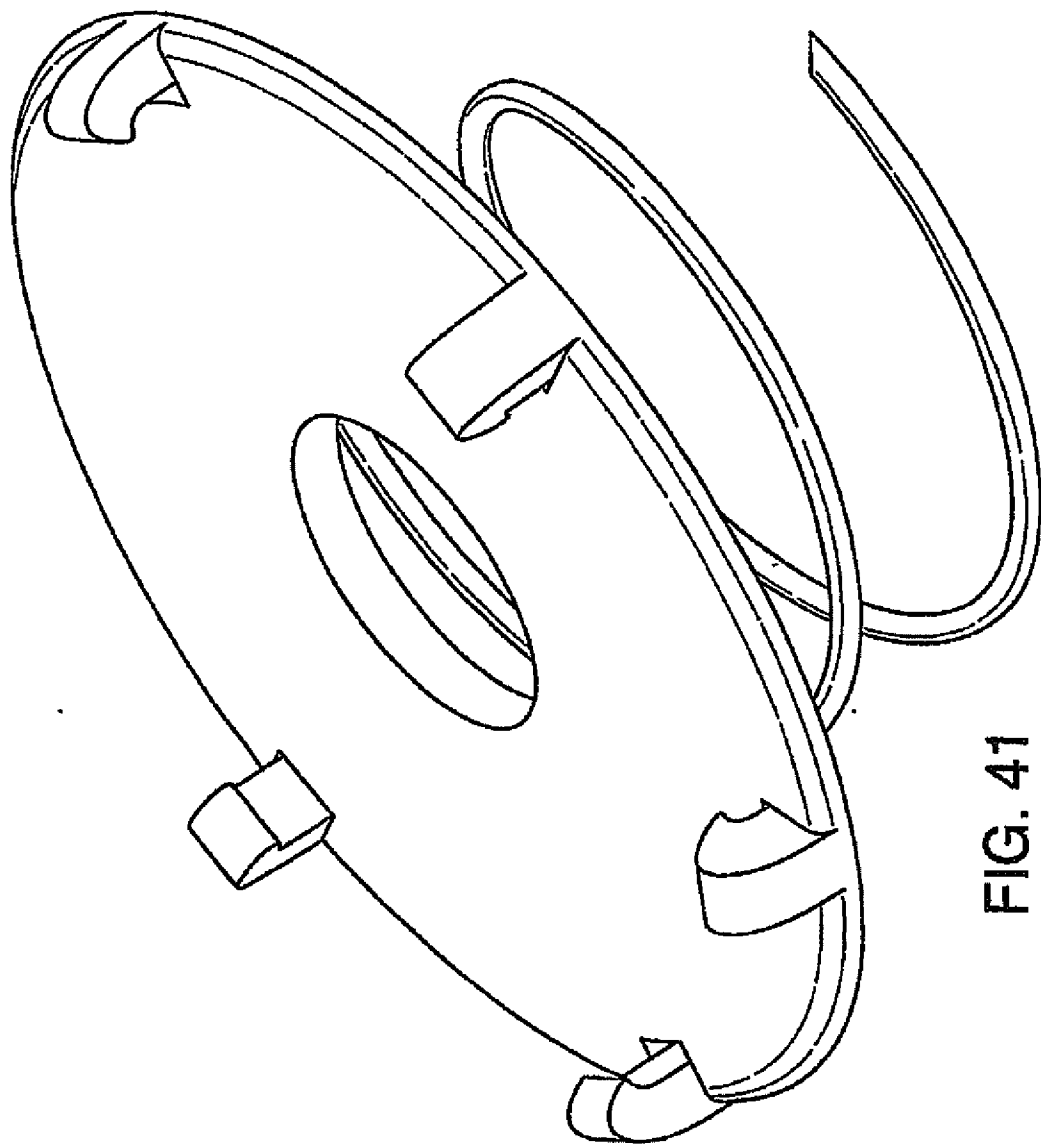


FIG. 41

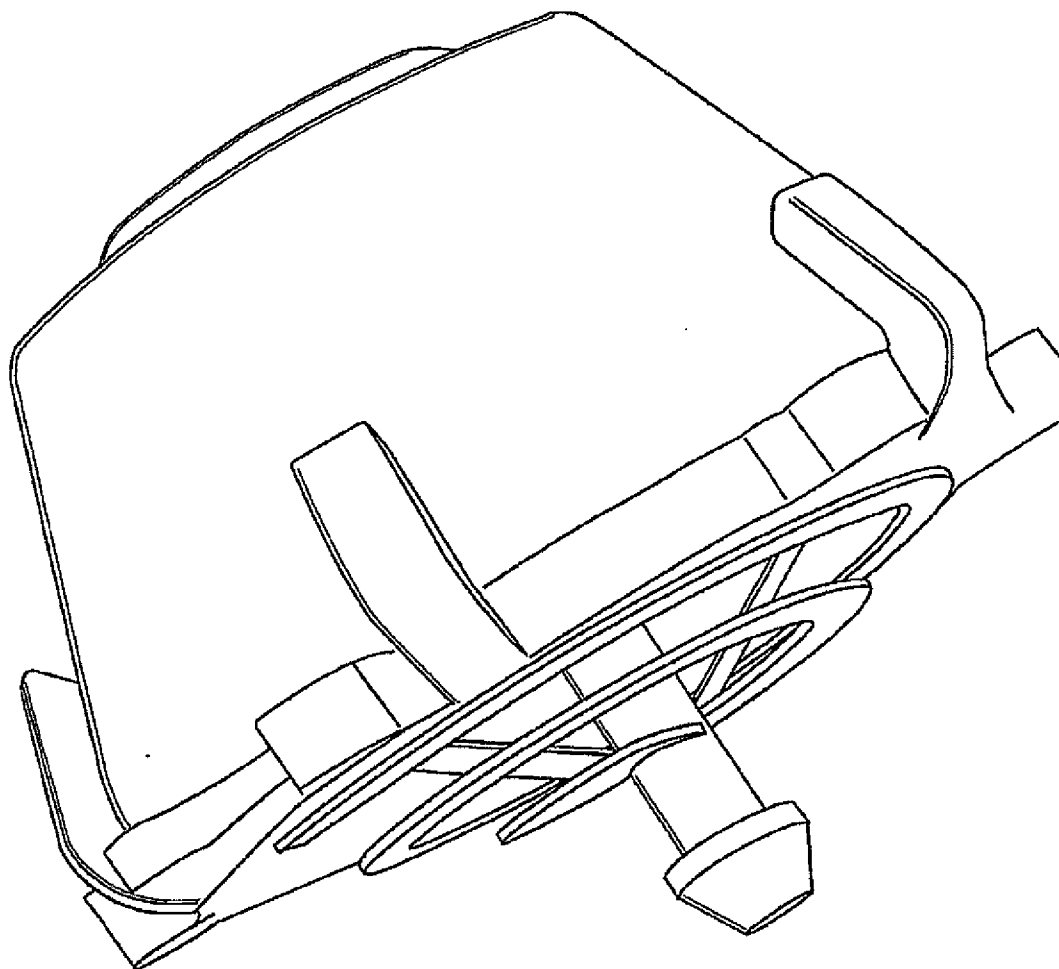


FIG. 42

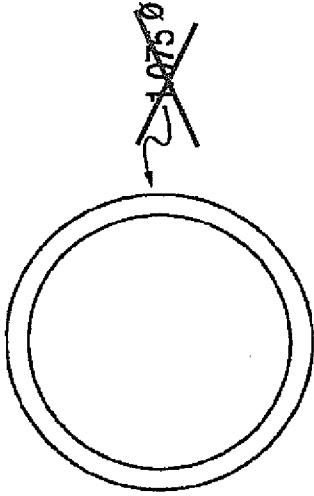


FIG. 43

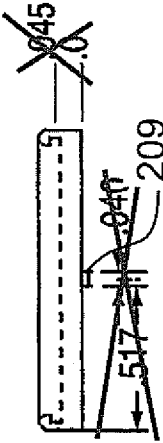


FIG. 44

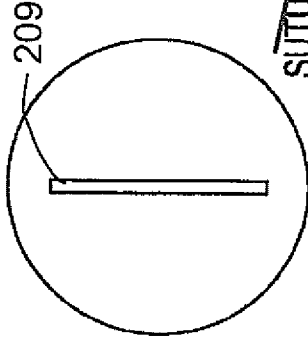


FIG. 45

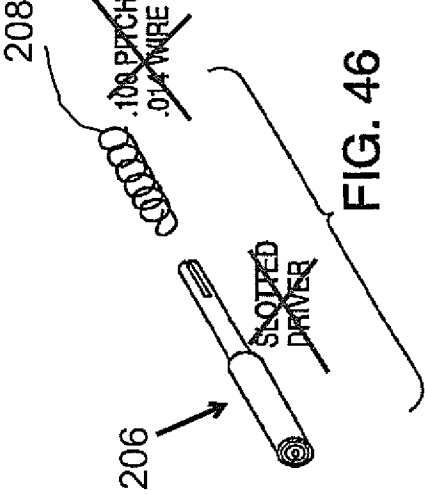


FIG. 46

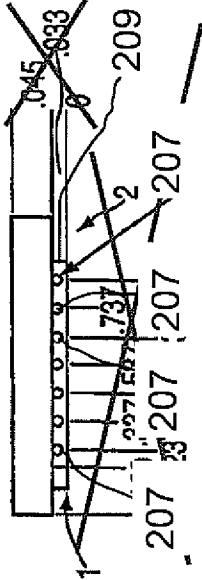
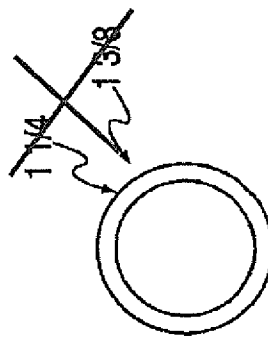


FIG. 47

- NOTES:
1. Should have solid stop.
 2. Could have latch by having driver end of spring catch on underside of base.



~~Should be~~



hole at either end of slot
Note.
use .2018 mandrel for
curved hooks

FIG. 48

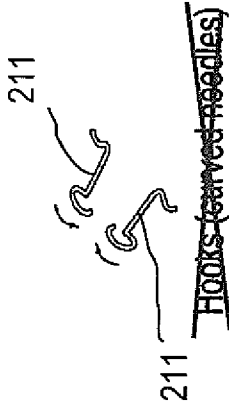


FIG. 51

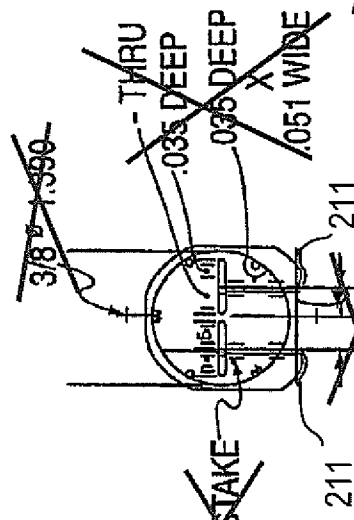


FIG. 49

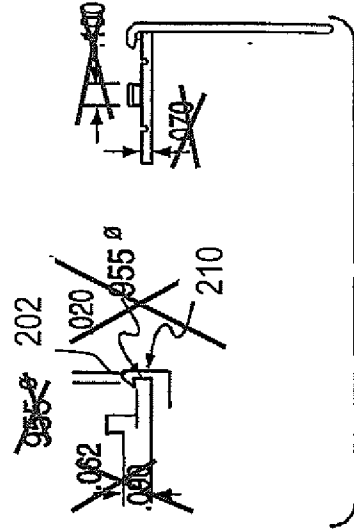


FIG. 50

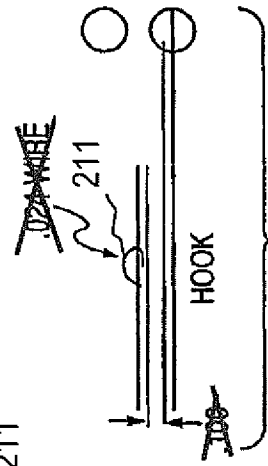


FIG. 52

~~PORTFIXATION PROTO #7~~

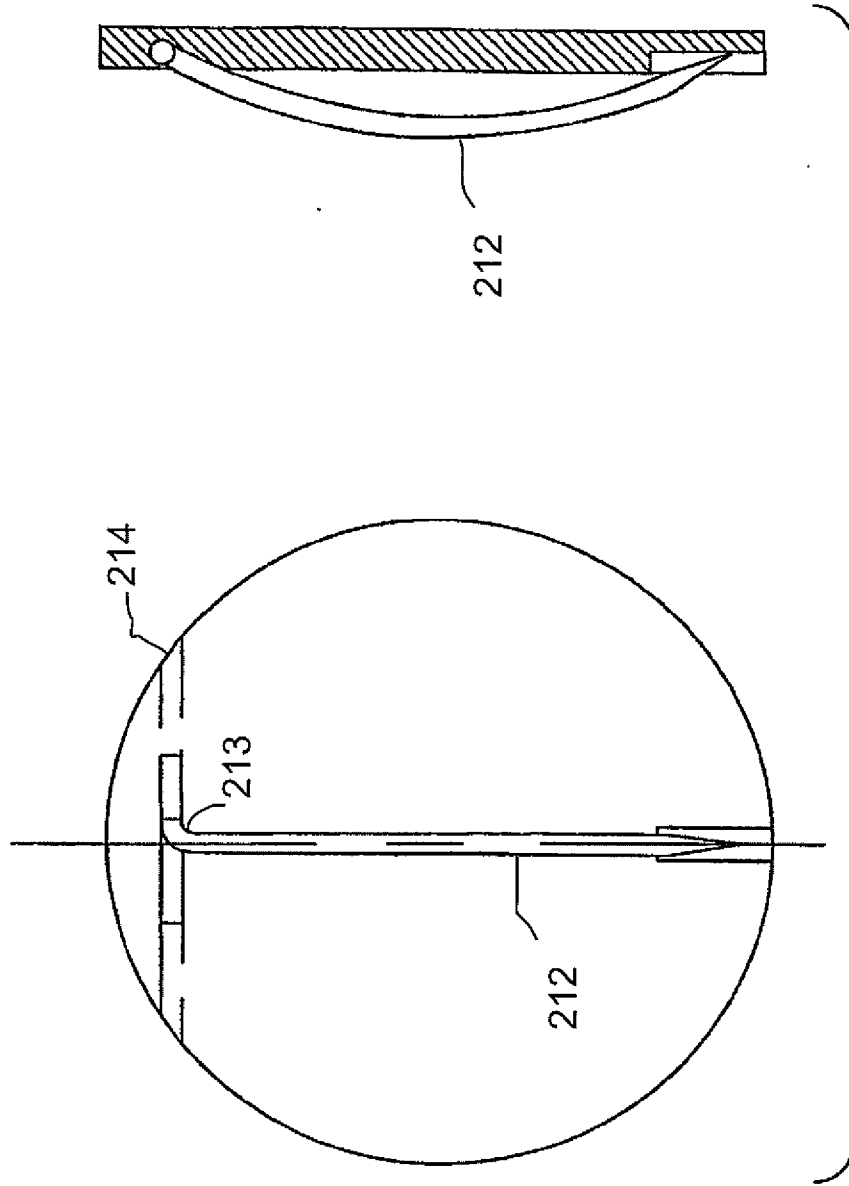


FIG. 53

~~PORE FIXATION PROTO # 8~~

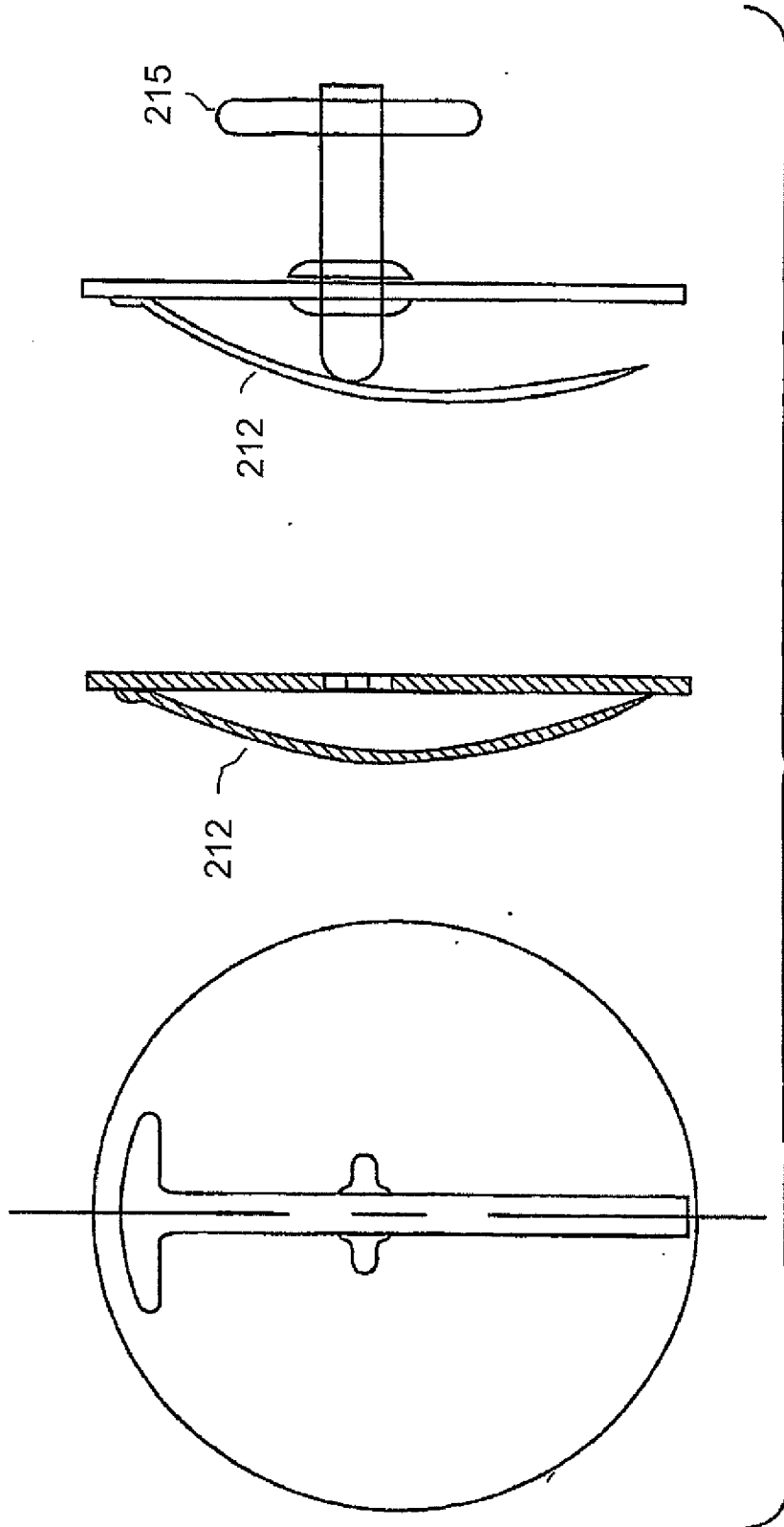


FIG. 54

ANNOTATED SHEET SHOWING CHANGES

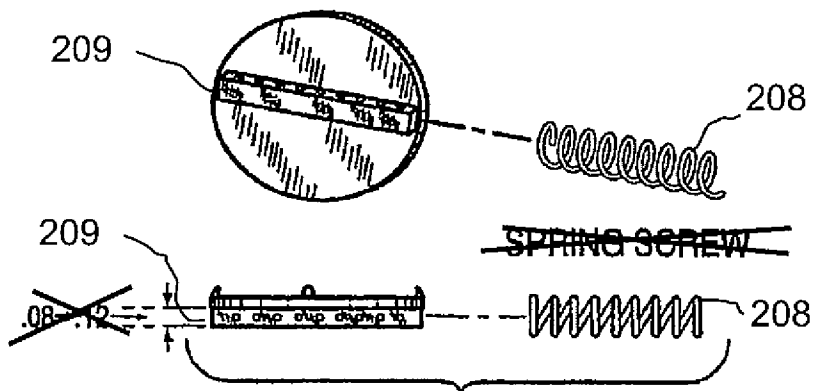


FIG. 55

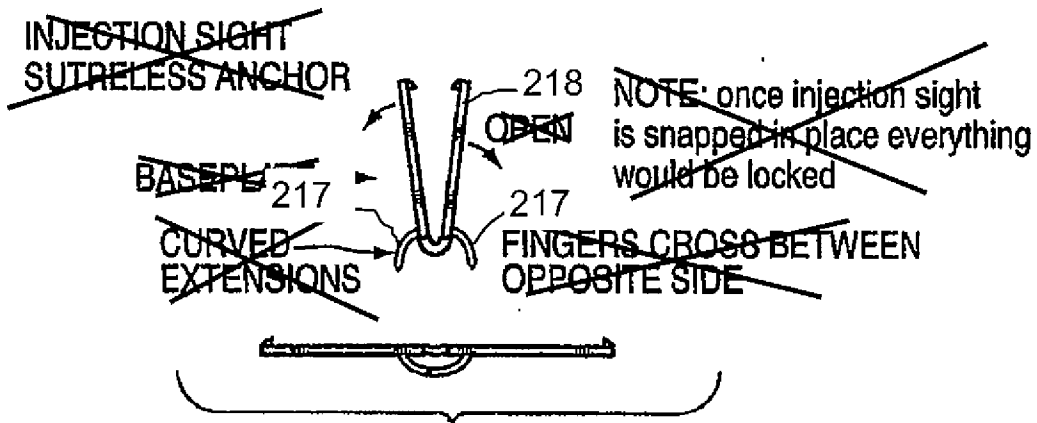


FIG. 56

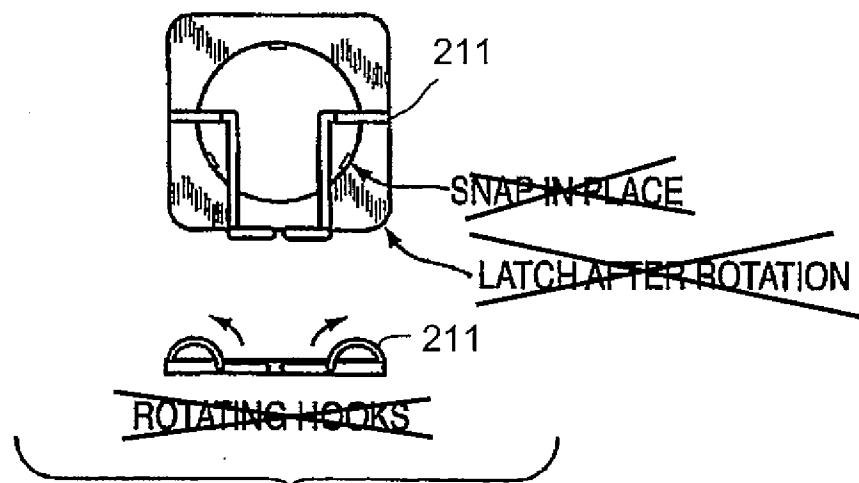


FIG. 57

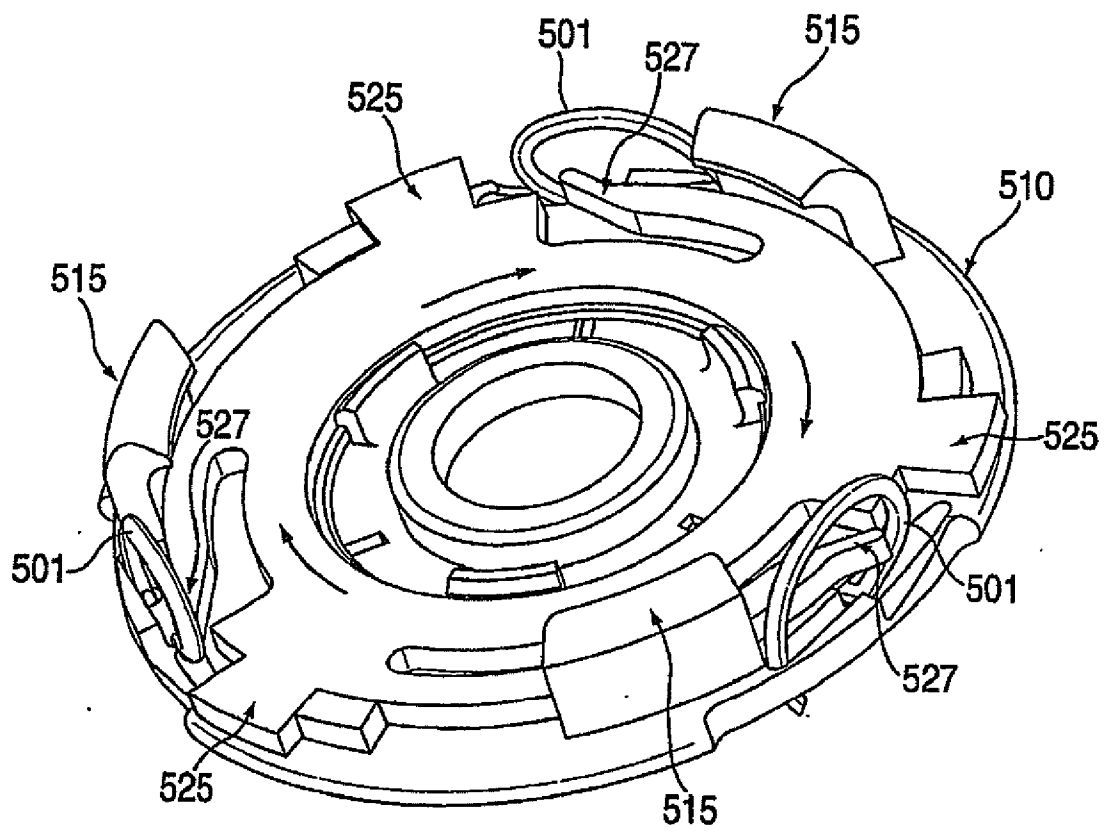


FIG. 58

